

PATENT COOPERATION TREATY

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REC'D 03 MAR 2005

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 899-63727	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US02/31944	International filing date (day/month/year) 24 September 2002 (24.09.2002)	Priority date (day/month/year) 10 January 2002 (10.01.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/00 and US Cl.: 514/12		
Applicant IMPERIAL COLLEGE INNOVATIONS LTD.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 07 April 2003(07.04.2003)	Date of completion of this report 28 January 2005 (28.01.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Sreenivasan Padmanabhan</i> Sreenivasan Padmanabhan Telephone No. 571.272.1600	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US02/31944

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:

pages 1-140 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☒ the claims:

pages 141-153, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☒ the drawings:

pages 1-9, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☐ the sequence listing part of the description:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US02/31944

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive Step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial Applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 6-19, 25-31, 33-38, 44-50, 52-57, 62-67, 71-76, 82-88, and 90-104 meet the criteria set out in PCT Article 33(2), because the prior art does not teach a method for decreasing calorie intake in a subject, comprising peripherally administering a therapeutically effective amount of PYY or an agonist thereof to the subject, thereby decreasing the calorie intake of the subject comprising specified dosage range set forth in the claims.

Claims 1-5, 20-24, 32, 39-43, 51, 58-61, 68-70, 77-81 and 89 lack novelty under PCT Article 33(2) as being anticipated by CROOM, JR et al. (US Patent No. 5,912,227 A). CROOM, JR et al. teach administration of PYY agonist peripherally as indetectable. CROOM, JR et al. teaches same method steps as claimed by Applicants by administration of same compound with same route of administration to a same subject therefore the effect decreasing calorie intake in a same subject would be inherent effect.

Claims 6-19, 25-31, 33-38, 44-50, 52-57, 62-67, 71-76, 82-88, and 90-104 lack an inventive step under PCT Article 33(3) as being obvious over CROOM, JR et al. (US Patent No. 5,912,227 A). CROOM, JR et al. teach administration of PYY agonist peripherally as injectables. CROOM, JR et al. do not teach the dosage range and specific PYY agonist. However, it would have been obvious to one of ordinary skill in the art to optimize the dosage to administer safe dosage for the peripheral administration.

Claims 1-104 meet the criteria set out in PCT Article 33(4), since a method for decreasing calorie intake in a subject, comprising peripherally administering a therapeutically effective amount of PYY or an agonist thereof to the subject, thereby decreasing the calorie intake of the subject comprising specified dosage range set forth in the claims have an industrial applicability in pharmaceutical industry.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 6-19, 25-31, 33-38, 44-50, 52-57, 62-67, 71-76, 82-88, 90-104

The opinion as to Novelty was negative (No) with respect to claims 1-5, 20-24, 32, 39-43, 51, 58-61, 68-70, 77-81, 89

The opinion as to Inventive Step was positive (Yes) with respect to claims NONE

The opinion as to Inventive Step was negative (NO) with respect to claims 1-104

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-104

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

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NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No. PCT/US02/31944	Applicant's or agent's file reference 899-63727	Date of informal communication (day/month/year) 28 January 2005 (28.01.2005)
Applicant IMPERIAL COLLEGE INNOVATIONS LTD.		


<u>Communication</u> <input checked="" type="checkbox"/> by telephone <input type="checkbox"/> personal	<u>Participants</u> <input checked="" type="checkbox"/> Applicant: IM/PER,IAL COLLEGE INNOVATIONS LTD. <input checked="" type="checkbox"/> Agent: Ms. Susan Siegel <input checked="" type="checkbox"/> Examiner(s): Sreenivasan Padmanabhan	<input checked="" type="checkbox"/> Identity checked <input checked="" type="checkbox"/> authorization checked <input type="checkbox"/> personally known
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Summary of communication:

The attorney of record Ms. Susan Siegel informed Dr. Padmanabhan to prepare International Preliminary Report (409) and skip the Written Opinion (408).

- ☐ An extension of time limit is granted (Form PCT/IPEA/427).
- ☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424.

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Sreenivasan Padmanabhan Telephone No. (571) 272.1600
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